

Exhibit 300: Capital Asset Plan and Business Case Summary

Part I: Summary Information And Justification (All Capital Assets)

Section A: Overview

1. **Date of Submission:** 2011-02-28

2. **Agency:** 009

3. **Bureau:** 10

4. **Name of this Investment:** FDA MedWatch Plus

5. **Unique Project (Investment) Identifier (UPI):** 009-10-01-03-01-0042-00

6. **What kind of investment will this be in FY 2012?:** Mixed Life Cycle

- Planning
- Full Acquisition
- Operations and Maintenance
- Mixed Life Cycle
- Multi-Agency Collaboration

7. **What was the first budget year this investment was submitted to OMB?** FY2009

8.

- a. **Provide a brief summary of the investment and justification, including a brief description of how this closes in part or in whole an identified agency performance gap, specific accomplishments expected by the budget year and the related benefit to the mission, and the primary beneficiary(ies) of the investment.**

The Food and Drug Administration (FDA) is responsible for monitoring the safety of FDA regulated products in order to protect and promote public health. Analysis of adverse event and safety report information is critical to achieving this goal. The FDA needs to modernize its aging systems, improve its analytic capabilities, and make it easier for the public to submit adverse event and safety reports to the FDA. This investment was comprised of two primary efforts: the FDA adverse event reporting system (FAERS) and the public-facing reporting portal known as the Safety Reporting Portal (SRP—formerly known as MedWatch Plus Portal) and a unified core processing process/systems. FAERS will deliver the “back-end” application and database for data that supports post-market safety surveillance analysis for FDA regulated products. SRP and the core processing were to be the “front-end”, enabling a reporter to submit voluntary or mandatory reports to FDA on any regulated product. Core processing would provide services to ensure the data was complete and ready for analysis and public release. FDA conducted an internal assessment of the investment in late 2009. The assessment findings indicated that the project was too complex, difficult to manage, understaffed, and that the technical feasibility of a single system for all product types was questionable. It also noted that the current SRP concept depends on external factors for which FDA has limited control, including development and operation of the SRP system and questionnaires by the National Institutes of Health. Changes to the implementation approach include: FAERS and SRP are to be separated into two different investments FDA is shifting to a more outcome-focused operating model as recommended and has developed a FAERS schedule that will provide operational releases in 6 month intervals to establish a regular cadence of delivering outcomes. FDA has appointed a senior Lead PM, with 25+ year’s experience, as the single responsible person for the successful execution of the project. FDA has been transitioning from its current classic single-system, single-server architecture to a cloud architecture. The new FAERS will be implemented in the FDA Contractor Hosted Data Center in a private cloud environment, realizing operating cost avoidances.

- b. **Provide any links to relevant websites that would be useful to gain additional information on the investment including links to GAO and IG reports.**

Title	Link
NONE	

9.

- a. **Provide the date of the Agency's Executive/Investment Committee approval of this investment.**
2008-07-21
- b. **Provide the date of the most recent or planned approved project charter.** 2010-08-16

10. Contact information?

- a. **Program/Project Manager Name:** *
Phone Number: *
Email: *
- b. **Business Function Owner Name (i.e. Executive Agent or Investment Owner):** Slack, Mary Ann
Phone Number: *
Email: *

11. What project management qualifications does the Project Manager have? (choose only one per FAC-P/PM or DAWIA): Project manager qualifications according to FAC-P/PM or DAWIA criteria is under review for this investment.

- Project manager has been validated according to FAC-P/PM or DAWIA criteria as qualified for this investment.
- Project manager qualifications according to FAC-P/PM or DAWIA criteria is under review for this investment.
- Project manager assigned to investment, but does not meet requirements according to FAC-P/PM or DAWIA criteria.
- Project manager assigned but qualification status review has not yet started.
- No project manager has yet been assigned to this investment.

Section B: Summary of Funding (Budget Authority for Capital Assets)

1.

Table I.B.1: Summary of Funding
(In millions of dollars)

(Estimates for BY+1 and beyond are for planning purposes only and do not represent budget decisions)

	PY-1 and earlier	PY 2010	CY 2011 (CY Continuing Resolution)	BY 2012	BY+1 2013	BY+2 2014	BY+3 2015	BY+4 and beyond	Total
Planning:	*	*	*	*	*	*	*	*	*
Acquisition:	*	*	*	*	*	*	*	*	*
Planning & Acquisition Government FTE Costs	*	*	*	*	*	*	*	*	*
Subtotal Planning & Acquisition(DME):	*	*	*	*	*	*	*	*	*
Operations & Maintenance:	*	*	*	*	*	*	*	*	*
Disposition Costs (optional):	*	*	*	*	*	*	*	*	*
Operations, Maintenance, Disposition Government FTE Costs	*	*	*	*	*	*	*	*	*
Subtotal O&M and Disposition Costs (SS):	*	*	*	*	*	*	*	*	*
TOTAL FTE Costs	*	*	*	*	*	*	*	*	*
TOTAL (not including FTE costs):	*	*	*	*	*	*	*	*	*
TOTAL (including FTE costs):	*	*	*	*	*	*	*	*	*
Number of FTE represented by	*	*	*	*	*	*	*	*	*

Table I.B.1: Summary of Funding
(In millions of dollars)

(Estimates for BY+1 and beyond are for planning purposes only and do not represent budget decisions)

	PY-1 and earlier	PY 2010	CY 2011 (CY Continuing Resolution)	BY 2012	BY+1 2013	BY+2 2014	BY+3 2015	BY+4 and beyond	Total
Costs:									

2. Insert the number of years covered in the column “PY-1 and earlier”: 3

3. Insert the number of years covered in the column “BY+4 and beyond”: *

4. If the summary of funding has changed from the FY 2011 President’s Budget request, briefly explain those changes:

*

Section C: Acquisition/Contract Strategy (All Capital Assets)

1.

Table I.C.1 Contracts Table

Contract Status	Contracting Agency ID	Procurement Instrument Identifier (PIID)	Indefinite Delivery Vehicle (IDV) Reference ID	Solicitation ID	Alternative financing	EVM Required	Ultimate Contract Value (M)	Type of Contract/Task Order (Pricing)	Is the contract a Performance Based Service Acquisition (PBSA)?	Effective date	Actual or expected End Date of Contract/Task Order	Extent Completed	Short description of acquisition
Awarded		HHSF223200830363 G			*	*	\$0.5	Time and Materials	N	2010-07-22	2011-07-21		
Awarded		HHSF223200750669 G			*	*	\$4.8	Time and Materials	N	2007-09-24	2011-03-11		
Awarded		HHSF223201000014I		10223SOL00043	*	*	\$3.4	Firm Fixed Price	Y	2010-03-23		N	ADVERSE EVENT REPORTING SYSTEM (AERS) + 1 OPTION YEAR. SERVICES TO BE PERFORMED IN ACCORDANCE WITH SOW FOUND IN SECTION C.
Awarded		HHSF223200950026I			*	*	\$12.6	Time and Materials	N	2009-09-17		N	FDA HL7 DATA EXCHANGE SERVICE IDIQ

Table I.C.1 Contracts Table

Contract Status	Contracting Agency ID	Procurement Instrument Identifier (PIID)	Indefinite Delivery Vehicle (IDV) Reference ID	Solicitation ID	Alternative financing	EVM Required	Ultimate Contract Value (M)	Type of Contract/Task Order (Pricing)	Is the contract a Performance Based Service Acquisition (PBSA)?	Effective date	Actual or expected End Date of Contract/Task Order	Extent Completed	Short description of acquisition
Awarded		HHSF22320095002I			*	*	\$2.5	Time and Materials	N	2010-09-30	2015-09-29		CONTRACT

2. If earned value is not required or will not be a contract requirement for any of the contracts or task orders above, explain why:

*

3.

- a. Has an Acquisition Plan been developed? If yes, please answer the questions that follow *
- b. Does the Acquisition Plan reflect the requirements of FAR Subpart 7.1 *
- c. Was the Acquisition Plan approved in accordance with agency requirements *
- d. If "yes," enter the date of approval? *
- e. Is the acquisition plan consistent with your agency Strategic Sustainability Performance Plan? *
- f. Does the acquisition plan meet the requirements of EOs 13423 and 13514? *
- g. If an Acquisition Plan has not been developed, provide a brief explanation.

*

Part II: IT Capital Investments

Section A: General

1.
 - a. Confirm that the IT Program/Project manager has the following competencies: configuration management, data management, information management, information resources strategy and planning, information systems/network security, IT architecture, IT performance assessment, infrastructure design, systems integration, systems life cycle, technology awareness, and capital planning and investment control. yes
 - b. If not, confirm that the PM has a development plan to achieve competencies either by direct experience or education.
2. Describe the progress of evaluating cloud computing alternatives for service delivery to support this investment. fda has been transitioning from its current classic single-system, single-server architecture to a cloud architecture. faers will be implemented in the contractor hosted data center in a private cloud environment realizing operating cost savings
3. Provide the date of the most recent or planned Quality Assurance Plan 2010-08-30
4.
 - a. Provide the UPI of all other investments that have a significant dependency on the successful implementation of this investment.
 - b. If this investment is significantly dependent on the successful implementation of another investment(s), please provide the UPI(s).
5. An Alternatives Analysis must be conducted for all Major Investments with Planning and Acquisition (DME) activities and evaluate the costs and benefits of at least three alternatives and the status quo. The details of the analysis must be available to OMB upon request. Provide the date of the most recent or planned alternatives analysis for this investment. 2011-04-30
6. Risks must be actively managed throughout the lifecycle of the investment. The Risk Management Plan and risk register must be available to OMB upon request. Provide the date that the risk register was last updated. 2010-08-12

Section B: Cost and Schedule Performance

Table II.B.1. Comparison of Actual Work Completed and Actual Costs to Current Approved Baseline:

Description of Activity	DME or SS	Agency EA Transition Plan Milestone Identifier	Planned Cost (\$M)	Actual Cost (\$M)	Planned Start Date	Actual Start Date	Planned Completion Date	Actual Completion Date	Planned Percent Complete	Actual Percent Complete
MW+ Program Mgmt Support (FY09 Funding)	DME	*	\$2.5	\$2.3	2009-04-01	2009-04-01	2010-03-31	2010-03-31	100.00%	100.00%
MW+ Program Mgmt Support (FY10 Funding)	DME	*	\$0.0	\$0.0	2010-04-01	2010-04-01	2010-04-01	2010-04-01	0.00%	0.00%
MW+ Program Mgmt Support (FY11 Funding)	DME	*	\$1.5	\$0.0	2011-04-01		2012-03-31		0.00%	0.00%
MW+ Program Mgmt Support (FY12 Funding)	DME	*	*	*	2012-04-01	*	2013-03-31	*	*	*
MW+ Program Mgmt FTE (FY09-12 Funding)	DME	*	\$0.8	\$0.8	2009-04-01	2009-04-01	2009-09-30	2009-09-30	100.00%	100.00%
MW+ Program Mgmt FTE (FY09-14 Funding)	SS	*	\$0.2	\$0.2	2009-04-01	2009-04-01	2009-09-30	2009-09-30	100.00%	100.00%
MW+ Hardware and Software (FY09 Funding)	DME	*	\$4.2	\$3.8	2009-04-01	2009-04-01	2010-03-31	2010-03-31	100.00%	100.00%
MW+ Hardware and Software (FY10 Funding)	SS	*	\$0.0	\$0.0	2010-04-01	2010-04-01	2010-04-01	2010-04-01	0.00%	0.00%
MW+ Hardware and Software (FY11 Funding)	SS	*	\$1.0	\$0.0	2011-04-01		2012-03-31		0.00%	0.00%
MW+ Hardware and Software (FY12-14 Funding)	SS	*	*	*	2012-04-01	*	2015-03-31	*	*	*

Table II.B.1. Comparison of Actual Work Completed and Actual Costs to Current Approved Baseline:

Description of Activity	DME or SS	Agency EA Transition Plan Milestone Identifier	Planned Cost (\$M)	Actual Cost (\$M)	Planned Start Date	Actual Start Date	Planned Completion Date	Actual Completion Date	Planned Percent Complete	Actual Percent Complete
MW+ Design, Build, Test, Training, and Implementation of Release 1	DME	*	\$3.9	\$3.3	2009-04-01	2009-04-01	2010-05-01	2010-05-01	100.00%	100.00%
MW+ Reqs Analysis, Design, Build, Test, Training, and Implementation Release 2 (FY09 & 10 Funding)	DME	*	\$0.0	\$0.0	2010-03-01	2010-03-01	2010-03-01	2010-03-01	0.00%	0.00%
MW+ Reqs Analysis, Design, Build, Test, Training, and Implementation of Release 3	DME	*	\$0.0	\$0.0	2010-04-01	2010-04-01	2010-04-01	2010-04-01	0.00%	0.00%
MW+ C&A and Security Activities (FY09 Funding)	DME	*	\$0.2	\$0.1	2009-04-01	2009-04-01	2010-03-31	2010-03-31	100.00%	100.00%
MW+ C&A and Security Activities (FY10 Funding)	DME	*	\$0.0	\$0.0	2010-04-01	2010-04-01	2010-04-01	2010-04-01	0.00%	0.00%
MW+ C&A and Security Activities (FY11 Funding)	DME	*	\$0.2	\$0.0	2011-04-01		2012-03-31		0.00%	0.00%
MW+ C&A and Security Activities (FY12 Funding)	DME	*	*	*	2012-04-01	*	2013-03-31	*	*	*
MW+ Operations and Maintenance (FY10 Funding)	SS	*	\$0.0	\$0.0	2010-04-01	2010-04-01	2010-04-01	2010-04-01	0.00%	0.00%
MW+ Operations and Maintenance (FY11 Funding)	SS	*	\$0.7	\$0.0	2011-04-01		2012-03-31		0.00%	0.00%
MW+ Operations	SS	*	*	*	2012-04-01	*	2015-03-31	*	*	*

Table II.B.1. Comparison of Actual Work Completed and Actual Costs to Current Approved Baseline:

Description of Activity	DME or SS	Agency EA Transition Plan Milestone Identifier	Planned Cost (\$M)	Actual Cost (\$M)	Planned Start Date	Actual Start Date	Planned Completion Date	Actual Completion Date	Planned Percent Complete	Actual Percent Complete
and Maintenance (FY12-14 Funding)										
MW+ Legacy Systems O & M (FY09-14 Funding)	SS	*	\$1.6	\$1.6	2009-04-01	2009-04-01	2010-03-31	2010-03-31	100.00%	100.00%
FAERS Program Mgmt Support (FY09 Funding)	DME	*	\$2.8	\$2.5	2009-04-01	2009-04-01	2010-03-31	2010-03-31	100.00%	100.00%
FAERS Program Mgmt Support (FY10 Funding)	DME	*	\$0.0	\$0.0	2010-04-01	2010-04-01	2010-04-01	2010-04-01	0.00%	0.00%
FAERS Program Mgmt Support (FY11 Funding)	DME	*	\$1.3	\$0.0	2011-04-01		2012-03-31		0.00%	0.00%
FAERS Program Mgmt Support (FY12 Funding)	DME	*	*	*	2012-04-01	*	2013-03-31	*	*	*
FAERS Program Mgmt FTE (FY09-12 Funding)	DME	*	\$0.8	\$0.8	2009-04-01	2009-04-01	2009-09-30	2009-09-30	100.00%	100.00%
FAERS Program Mgmt FTE (FY09-14 Funding)	SS	*	\$0.1	\$0.1	2009-04-01	2009-04-01	2009-09-30	2009-09-30	100.00%	100.00%
FAERS Hardware and Software (FY09 Funding)	DME	*	\$4.7	\$4.2	2009-04-01	2009-04-01	2010-03-31	2010-03-31	100.00%	100.00%
FAERS Hardware and Software (FY10 Funding)	SS	*	\$0.0	\$0.0	2010-04-01	2010-04-01	2010-04-01	2010-04-01	0.00%	0.00%
FAERS Hardware and Software (FY11 Funding)	SS	*	\$0.9	\$0.0	2011-04-01		2012-03-31		0.00%	0.00%

Table II.B.1. Comparison of Actual Work Completed and Actual Costs to Current Approved Baseline:

Description of Activity	DME or SS	Agency EA Transition Plan Milestone Identifier	Planned Cost (\$M)	Actual Cost (\$M)	Planned Start Date	Actual Start Date	Planned Completion Date	Actual Completion Date	Planned Percent Complete	Actual Percent Complete
FAERS Hardware and Software (FY12-14 Funding)	SS	*	*	*	2012-04-01	*	2015-03-31	*	*	*
FAERS Design, Build, Test, Training, and Implementation of Release 1	DME	*	\$5.9	\$5.7	2009-04-01	2009-04-01	2010-03-31	2010-03-31	100.00%	100.00%
FAERS Reqs Analysis, Design, Build, Test, Training, and Implementation Release 2 (FY09-10 Funding)	DME	*	\$0.0	\$0.0	2009-08-01	2009-08-01	2009-08-01	2009-08-01	0.00%	0.00%
FAERS Reqs Analysis, Design, Build, Test, Training, and Implementation of Release 3 (FY10 and 11 Funding)	DME	*	\$0.0	\$0.0	2010-04-01	2010-04-01	2010-04-01	2010-04-01	0.00%	0.00%
FAERS C&A and Security Activities (FY09 Funding)	DME	*	\$0.2	\$0.1	2009-04-01	2009-04-01	2010-03-31	2010-03-31	100.00%	100.00%
FAERS C&A and Security Activities (FY10 Funding)	DME	*	\$0.2	\$0.0	2010-04-01	2010-04-01	2011-03-31	2010-04-01	0.00%	0.00%
FAERS C&A and Security Activities (FY11 Funding)	DME	*	\$0.2	\$0.0	2011-04-01		2012-03-31		0.00%	0.00%
FAERS C&A and Security Activities (FY12 Funding)	DME	*	*	*	2012-04-01	*	2013-03-31	*	*	*
FAERS Operations and	SS	*	\$0.5	\$0.5	2009-04-01	2009-04-01	2010-03-31	2010-03-31	100.00%	100.00%

Table II.B.1. Comparison of Actual Work Completed and Actual Costs to Current Approved Baseline:

Description of Activity	DME or SS	Agency EA Transition Plan Milestone Identifier	Planned Cost (\$M)	Actual Cost (\$M)	Planned Start Date	Actual Start Date	Planned Completion Date	Actual Completion Date	Planned Percent Complete	Actual Percent Complete
Maintenance (FY09 Funding)										
FAERS Operations and Maintenance (FY10 Funding)	SS	*	\$0.0	\$0.0	2010-04-01	2010-04-01	2010-04-01	2010-04-01	0.00%	0.00%
FAERS Operations and Maintenance (FY11 Funding)	SS	*	\$0.7	\$0.0	2011-04-01		2012-03-31		0.00%	0.00%
FAERS Operations and Maintenance (FY12-14 Funding)	SS	*	*	*	2012-04-01	*	2015-03-31	*	*	*
Closed FY07-08 Milestones Summary - DME	DME	*	\$10.7	\$10.7	2007-11-01	2007-11-01	2009-03-31	2009-03-31	100.00%	100.00%

2. If the investment cost, schedule, or performance variances are not within 10 percent of the current baseline, provide a complete analysis of the reasons for the variances, the corrective actions to be taken, and the most likely estimate at completion. The scope of MedWatch Plus/FAERS project has expanded to include functionality and interfaces for the Center for Food Safety and Applied Nutrition (CFSAN) and the Center for Veterinary Medicine (CVM).

3. For mixed lifecycle or operations and maintenance investments an Operational Analysis must be performed annually. Operational analysis may identify the need to redesign or modify an asset by identifying previously undetected faults in design, construction, or installation/integration, highlighting whether actual operation and maintenance costs vary significantly from budgeted costs, or documenting that the asset is failing to meet program requirements. The details of the analysis must be available to OMB upon request. Insert the date of the most recent or planned operational analysis.

4. Did the Operational analysis cover all 4 areas of analysis: Customer Results, Strategic and Business Results, Financial Performance, and Innovation?

Section C: Financial Management Systems

Table II.C.1: Financial Management Systems			
System(s) Name	System acronym	Type of Financial System	BY Funding
*	*	*	*

Section D: Multi-Agency Collaboration Oversight (For Multi-Agency Collaborations only)

Table II.D.1. Customer Table:	
Customer Agency	Joint exhibit approval date
NONE	

Table II.D.2. Shared Service Providers		
Shared Service Provider (Agency)	Shared Service Asset Title	Shared Service Provider Exhibit 53 UPI (BY 2011)
*	*	*

Table II.D.3. For IT Investments, Partner Funding Strategies (\$millions):							
Partner Agency	Partner exhibit 53 UPI (BY 2012)	CY Monetary Contribution	CY “In-Kind” Contribution	CY Fee-for-Service	BY Monetary Contribution	BY “In-Kind” Contribution	BY Fee-for-Service
NONE							

Table II.D.4. Legacy Systems Being Replaced		
Name of the Legacy Investment of Systems	Current UPI	Date of the System Retirement
*	*	*

Section E: Performance Information

Table I.E.1a. Performance Metric Attributes

Measurement Area (For IT Assets)	Measurement Grouping (For IT Assets)	Measurement Indicator	Reporting Frequency	Unit of Measure	Performance Measure Direction	Baseline	Year Baseline Established for this measure (Origination Date)
Processes and Activities	Efficiency	Average processing time will be reduced for converting a voluntary paper AE report into a verified/usable record in a database.	quarterly	Hours	Decrease	14 days	2007-09-30
Technology	Accessibility	Increase in the percentage of all Adverse Event (AE) reports submitted electronically compared to all AE reports	annual	Individual Reports	Increase	45%	2007-09-30

		submitted					
			Fiscal Year	Target	Actual Results	Target "Met" or "Not Met"	Last Updated
			2008	55%	55%		2010-09-17
			2009	60%	55%	Not Met	2010-10-29
			2010	65%	65%	Met	2010-10-29
			2011	69%	TBD		2010-09-17
			2012	72%	TBD		2010-09-17
			2013	74%	TBD		2010-09-17
			2014	76%	TBD		2010-09-17
			2015	78%	TBD		2010-09-17
Customer Results	Customer Impact or Burden	Increase in the percentage of reports via the user friendly, web-based, single-step rational questionnaire vs. the percentage submitted via the multi-step paper process by voluntary reporters	semi-annual	Percent	Increase	51%	2007-09-30
			Fiscal Year	Target	Actual Results	Target "Met" or "Not Met"	Last Updated
			2008	53%	53%		2010-09-17
			2009	55%	0%	Not Met	2010-10-29

			2010	55%	55%	Met	2010-10-29
			2011	56%	TBD		2010-09-17
			2012	65%	TBD		2010-09-17
			2013	66%	TBD		2010-09-17
			2014	67%	TBD		2010-09-17
Mission and Business Results	Population Health Management and Consumer Safety	Increase in the total number of reports via the user friendly, web-based, single-step rational questionnaire vs. the number submitted via the multi-step paper process by voluntary reporters	2015	68%	TBD		2010-09-17
			semi-annual	Individual Reports	Increase	18,551	2007-09-30
			Fiscal Year	Target	Actual Results	Target "Met" or "Not Met"	Last Updated
			2014	19,107	TBD		2010-09-17
			2015	19,698	TBD		2010-09-17
Mission and Business Results	Population Health Management and Consumer Safety	increase in total number of voluntary reports received for FDA regulated products submitted by subject matter professionals	semi-annual	Individual Reports	Increase	15105	2007-09-30

			Fiscal Year	Target	Actual Results	Target "Met" or "Not Met"	Last Updated
			2008	15,558	19,038		2010-09-17
			2009	15,350	0	Not Met	2010-10-29
			2010	15,558	15,558	Met	2010-10-29
			2011	17,153	TBD		2010-09-17
			2012	18,011	TBD		2010-09-17
			2013	18,551	TBD		2010-09-17
Mission and Business Results	Population Health Management and Consumer Safety	Reduce unit cost associated with turning a submitted Adverse Event Report into a verified record in a database	annual	Dollars	Decrease	\$15	2007-09-30
			Fiscal Year	Target	Actual Results	Target "Met" or "Not Met"	Last Updated
			2008	\$13	\$13		2010-09-17
			2009	\$12.50	\$13	Not Met	2010-10-29
			2010	\$10.90	\$10.90	Met	2010-10-29
			2011	\$10.30	TBD		2010-09-17
			2012	\$9.60	TBD		2010-09-17
			2013	\$9.10	TBD		2010-09-17

2014	\$8.60	TBD		2010-09-17
2015	\$8.10	TBD		2010-09-17

* - Indicates data is redacted.